510(k) Premarket Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

1. DEVICE NAME:

Magnetic Resonance Diagnostic Device Accessory

Model Number:

MRT-1501 /P3

Trade/Proprietary Name:

EXCELART™ with Pianissimo

2. ESTABLISHMENT REGISTRATION:

2636923

3. U.S. AGENT NAME AND ADDRESS:

Toshiba America MRI, Inc.

280 Utah Avenue

South San Francisco, CA 94080

CONTACT PERSON:

Ken Nehmer

(650)872-2722 ext. 6083

4. MANUFACTURING SITE:

Toshiba Corporation 1385 Shimoisigami Otawara-shi, Tochigi-Ken

Japan 324

5. DATE OF SUBMISSION:

August 11, 2000

6. DEVICE DESCRIPTION:

This submission consists of a new Magnetic Resonance Imaging system which is based primarily on the cleared EXCELART™ w/Pianissimo (K993803) with the following new

functionality added to the standard system.

• Increase in maximum gradient field strength from 23 mT/m

to 25 mT/m

Increase in maximum gradient slew rate from 46 mT/m/ms

to 130 mT/m/ms

Increase in host computer memory from 192MB to 512MB
 Increase in host computer hard disk drive from 2.5GB to

9.0GB

• Increase in host computer MOD storage disk from 2.3GB

to 4.1GB

7. SAFETY PARAMETERS:

Maximum static field strength: Rate of change of magnetic field: Maximum radio frequency power Acoustic noise levels (maximum): EXCELART™ EXCELART™ MRT-1500/P2

1.5T 19.35 T/sec.

<1.5 W/kg

86.0 dB

EXCELART™ MRT-1501/P3

1.5T

19.3 T/sec.

<1.5 W/kg

95.0 dB

Acoustic noise data was measured in accordance with NEMA guidelines.

8. IMAGING PERFORMANCE PARAMETERS:

Specification volume: Head:

EXCELART™

Body:

16cm dsv* 28cm dsv*

^{*} Same as previously cleared with initial EXCELART™ system (K990620).

K002531 89192

9. INTENDED USE

Anatomical regions: Head, abdomen, breast, heart, pelvis, joints, neck, TMJ, spine, blood vessels,

limbs, and extremities

Nuclei excited:

Hydrogen

Diagnostic use:

Diagnostic imaging of the whole body (including head, abdomen, breast, heart, pelvis, joints, neck, TMJ, spine, blood vessels, limbs, and extremities), fluid visualization, 2D and 3D imaging, MR angiography/MR Vascular Imaging and MR fluoroscopy, Blood Oxygenation Level Dependent (BOLD) Imaging, Diffusion Imaging. [Application terms include MRCP (MR Cholangiopancreatography), MR Cisternography, MR Urography, MR Myelography, SAS (Surface Anatomy

Scan), Dynamic Scan, Cine Imaging, and Cardiac Tagging.]

10. EQUIVALENCY INFORMATION:

Toshiba America MRI, Inc. (TAMI), believes that the EXCELART™ with Pianissimo (model MRT-1501/P3) Magnetic Resonance Imaging (MRI) system is substantially equivalent to the EXCELART with Pianissimo (model MRT-1500/P2) Magnetic Resonance System (K993803) cleared on February 4, 2000.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

OCT 2 6 2000

Ken Nehmer Manager, Regulatory Affairs/Quality Systems Toshiba America MRI, Inc. 280 Utah Avenue South San Francisco, CA 94080 Re: K002531

EXCELART™ with Pianissimo (model MRT-1501/P3) Magnetic Resonance Imaging System

Dated: August 11, 2000 Received: August 16, 2000 Regulatory class: II

21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Nehmer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D. Captain, USPHS

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

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510(k)	Number (if known):	K002531	
	Name:	EXCELART™ with Pianissimo (model	MRT-1501/P3)
	ions for Use:		
Imaging of:			
magni	-		
	The Whole Body (including head, abdomen, breast, heart, pelvis, joints, neck, TMJ, spine, blood vessels, limbs and extremities). [Application terms include MRCP (MR Cholangiopancreatography), MR Cisternography, MR Urography, MR Myelography, MR Fluoroscopy, SAS (Surface Anatomy Scan), Dynamic Scan, Cine Imaging, and Cardiac tagging.]		
	Fluid Visualization		
	2D/3D Imaging		
	MR Angiography/MR Vascular Imaging		
	Blood Oxygenation Level Dependent (BOLD) Imaging		
	Diffusion Imaging		
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